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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/523,585 | 03/10/2000 | Christopher G M Ken | 290252020501 | 5888 |

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[REDACTED] EXAMINER

PANTUCK, BRADFORD C

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

3731

DATE MAILED: 07/30/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|--|--------------------------------|------------------|
| | Application No. | Applicant(s) |
| | 09/523,585 | KEN ET AL. |
| | Examiner Bradford C Pantuck | Art Unit 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04/03/2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 31-44 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 31-44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1)<input type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____. |
|--|---|

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/23/03 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-33, 35, and 37-44 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,354,295 to Guglielmi et al.

1. Regarding Claim 31, Guglielmi discloses in Fig. 3 a retainer deliverable via a tubular device (44) comprising a core wire (42) and a joint (element 50 or 54: both joints), which is electrolytically severable upon application of a current (col. 5, lines 44-47 and col. 6, lines 19-20). Both joints, 50 and 54, extend between the distal end of the core wire and at least one array element (56). Guglielmi further discloses a retainer assembly (elements 56 and 58) comprising at least one array element (56). In

Figures 7 and 8, the retainer assembly has a first shape when retained within the tubular device (col. 4, lines 33-37) and a second shape when retainer assembly is not retained in tubular device (col. 4, lines 44-46) wherein at least one array element extends outwardly from the joint in the second shape. The array element (56) has a contour that resembles the inside concave shape of the aneurysm wall [see Attachment #1, and further explanation in *Response to Arguments*, below. In Fig. 5, the second shape is configured for retaining a vaso-occlusive device in an aneurysm. A coil can be introduced with devices such as the device of Guglielmi (see Abstract of U.S. Patent No. 5,639,277 to Mariant et al.). After electrolytic severance from core wire, the retainer assembly includes a residual joint (Fig. 5: element 46).

2. Regarding Claim 32, Guglielmi discloses the core wire covered with an electrical insulation layer (col. 6, lines 20-21).
3. Regarding Claim 33, Guglielmi discloses at least one array element comprising platinum (col. 7, line 67).
4. Regarding Claim 35, Guglielmi discloses at least one array element comprising stainless steel (col. 7, line 35).
5. Regarding Claim 37, Guglielmi discloses a portion of at least one array element covered by a radio-opaque material (col. 4, lines 29-30).
6. Regarding Claim 38, Guglielmi discloses the radio-opaque material being platinum (col. 4, lines 29-30; col. 7, line 67).

7. Regarding Claim 39, Guglielmi discloses in Figure 4 that when the retainer assembly is in the second deployed shape, at least one array element terminates from the joint (54). In Figure 3, the array element (56) terminates at the joint.
8. Regarding Claim 40, Guglielmi discloses in Figure 3 that when the retainer assembly is in second shape, the residual joint, which would be the portions between 50 and 54, is distal to the proximal deployed end.
9. Regarding Claim 41, Guglielmi discloses in Figure 4 that when the retainer assembly is in the second shape, the residual joint is on the proximal deployed end.
10. Regarding Claim 42, Guglielmi discloses in Figure 4 the proximal deployed end is distal to the proximal delivery end when the retainer is in the second deployed shape.
11. Regarding Claim 43, Guglielmi discloses in Figures 4 and 5 the secondary deployed shape approximating the shape of a vascular aneurysm.
12. Regarding Claim 44, Guglielmi discloses in Figures 1A and 4 the retainer assembly enclosing a volume and wherein the retainer contains a helically wound vaso-occlusive device (col. 9, lines 21-23). A coil can also be introduced wherein the device of Guglielmi is capable of retaining the coil. It is well known to introduce coils with devices such as the device of Guglielmi et al. (see Abstract of U.S. Patent No. 5,639,277 to Mariant et al.).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,295 to Guglielmi et al. in view of U.S. Patent No. 5,639,277 to Mariant et al.

13. Regarding Claim 34, Guglielmi discloses an implantable retainer but does not disclose at least one array element comprising tantalum. Mariant et al., however, disclose an analogous device using tantalum (col. 1, lines 53-55; col. 4, lines 13-18) in its composition. The use of tantalum is advantageous because of its radiopaque property, which allows one to observe and monitor the device's position. It is well known to compose a device out of radiopaque material for observation and would have been obvious to one of ordinary skill in the art at the time of the invention to compose an array element of Guglielmi et al. from tantalum as in Mariant et al. because this allows the array element to be supervised from outside the body.

14. Regarding Claim 36, Guglielmi discloses an implantable retainer, but does not disclose at least one array element comprising a super-elastic alloy. Mariant, however, discloses an analogous device comprised of a variety of materials. In Column 3, lines 66-67 and Column 4, lines 1-3 and 13-15, Mariant discloses alloys and elastic polymers such as polyethylene as being suitable materials for composing an array element. These materials are advantageous because they are biocompatible and flexible, which are both necessary for forming a vaso-occlusion. It is well known

to compose an array element used in a blood vessel of a super-elastic alloy and would have been obvious to one of ordinary skill in the art at the time of the invention to compose the array element of Guglielmi from a super-elastic alloy as in Mariant so that the array element would better conform to the vessel and be biocompatible.

Response to Arguments

15. Applicant's arguments filed March 3, 2003 have been fully considered but they are not persuasive. Via amendment, the Applicant added the phrase "and having a contour that resembles a shape of the aneurysm" to the first claim, further describing the retainer assembly. The Applicant argues that the reference document [U.S. Patent No. 5,354,295 to Guglielmi et al.] does not disclose a retainer assembly with a contour resembling the shape of the aneurysm:

The overall mass formed by the coil 56 has a shape that resembles the shape of the aneurysm, but the contour of the coil 56 itself does not resemble the shape of the aneurysm. Instead, the contour of the coil 56 travels within the aneurysm in a random configuration.

However, Guglielmi's retainer assembly (elements 56 and 58) does have a contour that resembles a shape of the aneurysm [see Attachment #1]. A contour is defined as "a surface, especially of a curving form." Guglielmi's retainer assembly

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(in the second deployed shape) has a curved surface that is of a very similar shape to the inside surface of the aneurysm—a concave-shaped arc.

The Applicant argues that “the contour of the coil 56 travels in a random configuration.” While this is true to some extent, it is also true that Guglielmi’s wire, which makes up the coil 56, is extremely thin (0.001-0.005 inches) and individual parts of the coil will conform to tissues they are pushed up against [Column 7, lines 64-66], causing the wire to have various contours resembling the contour of the inside of the aneurysm.

Guglielmi further explains that his retainer assembly (members 28 and 30) is made out of an extremely soft material and that it is *easily deformed to take the shape of the interior shape of the aneurysm* [Column 8, lines 3-13]. Therefore, not only will the overall mass of Guglielmi’s retainer assembly conform to resemble the interior of the aneurysm, but, correspondingly, various parts/contours/sections of the retainer assembly (28 and 30) will conform to resemble the interior of the aneurysm (particularly those parts that contact the interior of the aneurysm upon insertion).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP

BCP

July 28, 2003

Kevin T. Truong
KEVIN T. TRUONG
PRIMARY EXAMINER
7/28/03

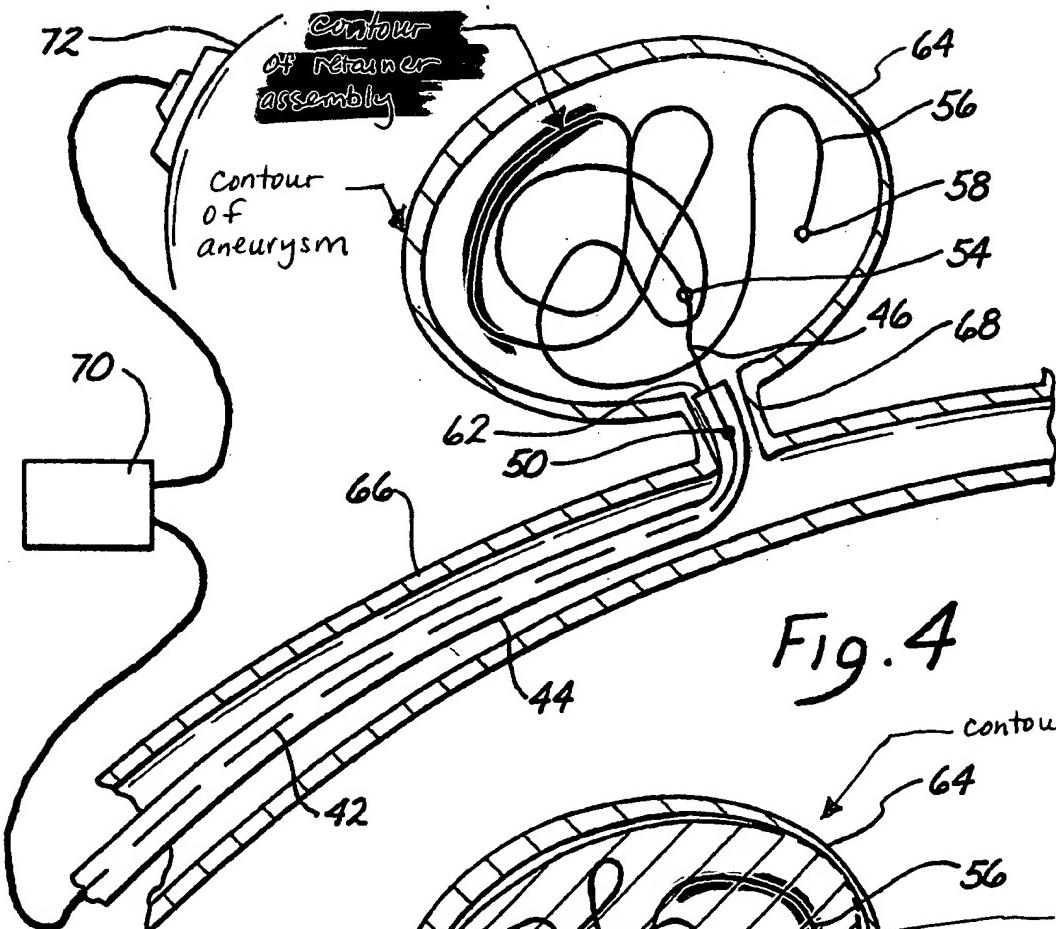


Fig. 4

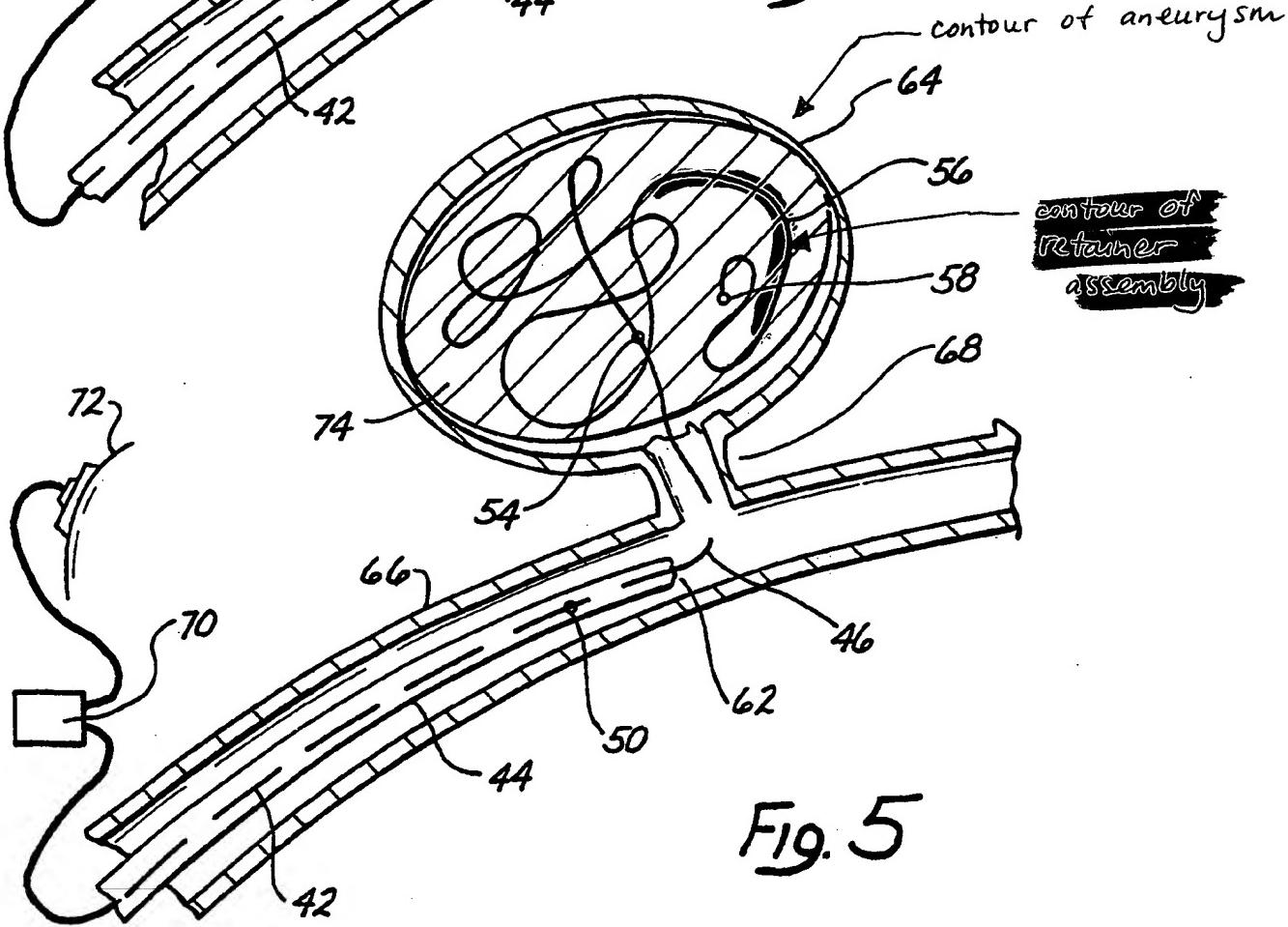


Fig. 5